K122039

DEC 27 2012

510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, Kettenbach GmbH & Co KG herewith submits a Summary of Safety and Effectiveness.

Name and address of manufacturer:

Kettenbach GmbH & Co KG
Im Heerfeld 7
35713 Eschenburg
Germany
Establishment Registration No.: 9681356
Owner/Operator Number: 9022134

Name, title and phone number of official correspondent:
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35713 Eschenburg
Germany
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Name, title and phone number of U.S. Agent (Contact):
Roggenbau, Wilfried
InterGest North America LLC.
400 Oser Ave., Suite 1650
Hauppauge, NY 11788
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Date of preparation: November 23, 2012

Device Identification:

Device Trade Name:	Kingscross
Versions:	B; PL-C+B-08; PL-C+B-10, PL-C+B-12
Common Name:	Temporary crown and bridge resin

Classification of the device:

Device Classification Name:	Crown And Bridge, Temporary, Resin
Product Code:	EBG
Device Classification No.:	Part 872.3770
Panel:	Dental
Regulatory Status:	Class II

Device Description:

Kingscross, which was developed by Kettenbach, is a highly esthetic composite of fabricating temporary restorations. The two-component system based on a multifunctional acryl composite is produced using no Bisphenol-A or Bisphenol-A precursors in the manufacturing process It has similar properties to a filling material and is available in the following shades:
A1, A2, A3, A3.5, B1, B3, Bleach white.
Kingscross temporary restorations can also be adjusted and customized using light-curing composites.

The two components (base and catalyst paste) are mixed by using a 50 ml cartridge at the ratio of 10:1 with a dispensing gun.

By varying the percentages of two chemical components in the base paste with different percentages of organic peroxide in the catalyst paste four different product variations with different mechanical properties are realized.

Intended Use:

Kingscross temporary crown and bridge material is intended to be used for fabrication of temporary prostheses, such as crowns, partial crowns, bridges, inlays, onlays and veneers, and for customization of prefabricated acrylic and metal crowns and for fabrication of long-term temporary restorations until a permanent restoration is fabricated.

Predicate devices:

Device Trade Name:	Integrity
Applicant:	Dentsply Intl.
510(k) No.:	K853052
Device Trade Name:	Luxatemp Ultra/Star
Applicant:	DMG USA, Inc.
510(k) No.:	K101710
Device Trade Name:	Luxatemp Automix
Applicant:	DMG CHEMISCH PHARMAZEUTISCHE FABRIK GMBH
510(k) No.:	K924830
Device Trade Name:	Protemp Plus
Applicant:	3M Espe
510(k) No.:	K073296

	Substantial Equivalent Devices				Predicate Devices			
	Kingscross				**Dentsply**	**DMG**	**DMG**	**3M Espe**
	B	**PL-C+B-12**	**PL-C+B-10**	**PL-C+B-08**	**Integrity**	**Luxatemp Star**	**Luxatemp Automix**	**Protemp Plus**
Intended Use	Kingscross temporary crown and bridge material is intended to be used for fabrication temporary prostheses, such as crowns, partial crowns, bridges, inlays, onlays and veneers, and for customization of prefabricated acrylic and metal crowns and for fabrication of long-term temporary restorations until a permanent restoration is fabricated.				For the fabrication of temporary crowns and bridges until the permanent restoration can be delivered.			
Application	2-paste-system (catalyst/base)				Same	Same	Same	Same
Mixing	Dispensing gun, cartridge, mixing tip				Same	Same	Same	Same
A comparison of parameters in respect to processing time (placement in mouth, removal from mouth, end of curing) was performed. The results demonstrated substantial equivalence to the predicate devices.								
A comparison of the mechanical properties has also been performed in respect to the parameters and standards referenced under "Summary of Non-Clinical Performance Testing". The results also demonstrate substantial equivalence to the predicate devices.								

The Kingscross temporary crown and bridges materials are considered substantially equivalent to the Protemp Plus (K073296), Dentsply Integrity (K853052), Luxatemp Ultra/Star (K101710) and Luxatemp Automix (K924830).
There is no significant difference in intended use or technology. Each version of the Kingscross material is substantially equivalent to the above listed predicate devices.

Summary of Non-Clinical Performance Testing:
Biocompatiblity tests have been performed to assure biological safety in accordance with the ISO 10993 family. Tests in respect to cytotoxicity (ISO 10993-5), mutagenicity (OECD 487), sensitization and mucosa irritation (ISO 10993-10) and a chemical analysis showed, that Kingscross materials' biocompatibility data is comparable to other materials on the market.
Additionally bench testing was performed to allow an evaluation of the mechanical properties of Kingscross in comparison to already marketed products. The evaluation covers

- E-Modulus (ADA/ANSI Specification No. 53, subclause 7.6)
- Flexible strength (ADA/ANSI Specification No. 53, subclause 7.6)
- Impact strength
- Compressive strength (ISO 9917-1, Annex D)
- Diametral tensile strength (ADA/ANSI Specification No. 27:1976)
- Volume shrinkage (DIN 13907)
- Max. temperature on cure
- Inhibition layer
- Extrusion force

The results indicate adequate strength results compared to leading temporary crown and bridge materials.

Conclusion:
Kettenbach GmbH & Co KG believes that the Kingscross temporary crown and bridge material is substantially equivalent to the currently legally marketed products. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 27, 2012

Mr. Juergen Berger
Regulatory Affairs Manager
Kettenbach GmbH & Company KG
Im Heerfeld 7
Eschenburg, Hessen
Germany 35713

Re: K122039
Trade/Device Name: Kingscross Temporary Crown and Bridge Material
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: December 12, 2012
Received: December 26, 2012

Dear Mr. Berger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K122039

Device Name: Kingscross temporary crown and bridge material

Indications for Use:
Kingscross temporary crown and bridge material is intended to be used for fabrication of temporary prostheses, such as crowns, partial crowns, bridges, inlays, onlays and veneers, and for customization of prefabricated acrylic and metal crowns and for fabrication of long-term temporary restorations until a permanent restoration is fabricated.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2012.12.27 11:28:05 -05'00' For Susan Runner, DDS

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122039